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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,077	06/01/2005	David Duncan Heath	JAMES68.008APC	8641
20995 7590 02/25/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER HOFFER, SUSANNA MARIE	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 02/25/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/517,077

Applicant(s)

HEATH, DAVID DUNCAN

Examiner

Susanna Hoffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-10, 31, and 32 in the reply filed on January 7, 2008 is acknowledged. Claims 12-28 and 32 have been canceled. Claims 1-10 and 31 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "hours, days, weeks, months and any combination there of," in Claim 5 does not constitute a predetermined period of time.

Claim 31 recites the limitation "wherein the sequentially increasing doses are 25, 50, 75, 100 or 4, 8, 32, 150 active units" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 31 is dependent upon claim 4 which requires sequentially doubling doses of biologically active agents, but the dosages of claim 31 do not sequentially double.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashmi et al. (WO 01/07079 A1).

The claims are to a process for administering one or more biologically active agents to an animal, comprising administering to said animal on a single occasion a form that releases at least three progressively increasing doses of said one or more biologically active agents over a predetermined period of time. Claim 2 is to the same process wherein one or more biologically active agents are selected from a group. Claim 3 is directed to the process of claim 1 wherein one or more biologically active agents comprise an adjuvant and/or pharmaceutically acceptable carrier. Claim 5 requires the doses to be administered in hours, days, weeks, and/or months. Claim 6 requires the active agents to be immunizing agents. Claims 7 and 8 require the immunizing agents to comprise an antigen or vaccine. Claim 9 requires the immunizing agents to induce protective or functional immunity.

Hashmi et al. teach a vaccine formulation providing for the extended release of antigenic material overtime, wherein a single administration will establish an active immunity in an animal (abstract). One embodiment of the invention comprises an initial sensitizing boosted release period followed by a booster at 3 months and a second

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booster at 9-15 months, which may have higher release rates (page 11, lines 5-14).

The antigenic substance may be dispersed in a pharmacologically acceptable carrier system (page 3, line 24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi et al. (WO 01/07079 A1).

Although Hashmi et al. do not specifically teach an example of what the increasing doses could be, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the increasing dosages as taught by Hashmi et al. through routine experimentation. One would have been motivated to experiment with dosage amounts to find the most effective process for vaccination.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Hoffer whose telephone number is (571)272-9345. The examiner can normally be reached on Monday - Friday, 9:00 a.m.-5:00 p.m., EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMH


MICHAEL R. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600